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DEA/FCE-1994

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|-----------------------------|-------------------------|-----------------------------------|-------------------------------------|
| SERIAL NUMBER<br>09/187,768 | FILING DATE<br>11/06/98 | FIRST NAMED APPLICANT<br>CINCUTTA | ATTORNEY DOCKET NO.<br>2291/18006-U |
|-----------------------------|-------------------------|-----------------------------------|-------------------------------------|

HM11/1117

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|                  |              |
|------------------|--------------|
| EXAMINER         |              |
|                  |              |
| ART UNIT<br>1542 | PAPER NUMBER |
| 11/17/99         |              |

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application  
Commissioner of Patents

# Office Action Summary

Application No.

09/187,768

Applicant(s)

Cincotta et al

Examiner

Ungar

Group Art Unit

1642



☒ Responsive to communication(s) filed on Nov 6, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire thirty days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 34-58 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 34-58 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Claims 34-58 are pending in the application and are currently under prosecution.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

**Group I.** Claims 34-54 are drawn to a method for arresting the growth of or eradicating tumors classified in Class 514, subclass 2.

**Group II.** Claims 55-56 are drawn to a kit comprising a photosensitizer classified in Class 430, subclass 581.

**Group III.** Claims 57 and 58 are drawn to a kit comprising a prolactin enhancer, classified in Class 530, subclass 300+.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions II/III as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

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The inventions of Groups II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the photosensitizer product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the prolactin enhancer products as claimed as claimed can be used in a materially different process such as affinity chromatography.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claim 34 is generic to a plurality of disclosed patentably distinct species comprising prolactin enhancers with different structures and functions wherein the enhancers are (a) prolactin and pharmaceutically acceptable salts thereof (claims 36 and 39) (b) melatonin and pharmaceutically acceptable salts thereof (claims 36, 37-38, 41, 42), (c) metoclopramide and pharmaceutically acceptable salts thereof

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(claim 36), (d) domperidone and pharmaceutically acceptable salts thereof (claim 36) and (e) 5-hydroxytryptophan and pharmaceutically acceptable salts thereof (claim 36). Claims 40 and 41 will be examined as drawn

6. Group I is further subject to election of a single disclosed species.

Claims 34 and 35 are generic to a plurality of disclosed patentably distinct species comprising photosensitizers with different structures and functions wherein the photosensitizers are (a) porphyrin dyes and pharmaceutically acceptable salts thereof (claims 43-48), (b) phthalocyanine dyes and pharmaceutically acceptable salts thereof (claim 43-48), (c) cyanine dyes and pharmaceutically acceptable salts thereof (claim 43-48), (d) benzophenoxazine analogs and pharmaceutically acceptable salts thereof (claim 43-48).

If species (d) is elected, species (d) is further subject to election of a single disclosed species.

7. Group I is further subject to election of a single disclosed species.

Claim 49 is generic to a plurality of benzophenoxazine analog's with different structures and functions wherein the analogs are (a) 5-ethylamino-9-diethylamino-2-iodobenzo[a]phenothiazinium chloride (claims 49-54), (b) 5-thylamino-0-diethylamino-benzo[a]phenothiazinium chloride (claims 49-54).

8. Group II is further subject to election of a single disclosed species.

Claim 56 is generic to a plurality of disclosed patentably distinct species comprising photosensitizers with different structures and functions wherein the photosensitizers are (a) porphyrin dyes and pharmaceutically acceptable salts thereof (claim 55), (b) phthalocyanine dyes and pharmaceutically acceptable salts thereof (claim 55), (c) cyanine dyes and pharmaceutically acceptable salts thereof

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(claim 55), (d) benzophenoxazine analogs and pharmaceutically acceptable salts thereof (claim 55).

9. Group III is further subject to election of a single disclosed species.

Claim 57 is generic to a plurality of disclosed patentably distinct species comprising prolactin enhancers with different structures and functions wherein the enhancers are (a) prolactin and pharmaceutically acceptable salts thereof (claim 58), (b) melatonin and pharmaceutically acceptable salts thereof (claim 58), (c) metoclopramide and pharmaceutically acceptable salts thereof (claim 58), (d) domperidone and pharmaceutically acceptable salts thereof (claim 58 and (e) 5-hydroxytryptophan and pharmaceutically acceptable salts thereof (claim 58)

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter

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of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

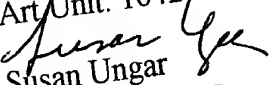
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

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Susan Ungar

Primary Patent Examiner

October 26, 1999





# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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